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EXAMINER	
HUANG, GIGI GEORGIANA	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/582,174	FUJIWARA ET AL.	
	Examiner	Art Unit	
	GIGI HUANG	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,6-11 and 13-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,6-11 and 13-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The response filed February 18, 2010 has been received, entered and carefully considered. The response affects the instant application accordingly:

   a. Claims 1, 10, 18-20, 22-23 have been amended.

   b. Claim 24-27 has been added.

2. Claims 1, 4, 6-11, 13-27 are pending in the case.

3. Claims 1, 4, 6-11, 13-27 are present for examination.

4. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.

5. All grounds not addressed in the action are withdrawn or moot.

6. New grounds of rejection are set forth in the current office action.

New Grounds of Rejection

Due to the amendment of the claims the new grounds of rejection are applied:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 26-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed,

had possession of the claimed invention. The claims recite a medicament-containing particle consisting of a medicament with an unpleasant taste, methyl cellulose, and mannitol with a ratio of 1 part medicament to about 0.8-about 10 parts wt. methylcellulose and a ratio of 1 part methylcellulose to about 0.3-about 12 parts wt. mannitol, and respectively: a binder and/or fluidization agent (claim 26) and 1-4 ingredients selected from the group consisting of a binder, a fluidization agent, a corrigent, and a disintegrant (claim 27). While Applicant does have support for the granule to be consisting of the specific combination of the drug, methylcellulose, and mannitol as addressed by claim 25 in the examples, the specification does not support the recitations of claims 26-27. While Applicant draws from Page 21 of the specification, the area of the specification is to the general inclusion as drawn for open language of a composition, not the closed language of consisting of these specific elements for the granule. This is a new matter rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recited the inclusion of a corrigent. It is unclear as to what materials fulfill this recitation. It does not allow one to ascertain the metes and bounds. For purposes of prosecution, any excipient will apply.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claim 1, 4, 6-7, 11, 13-20, 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siebert et al. (U.S. Pat. No. 6368625).

Siebert et al. teaches an oral disintegrable dosage form comprising an active ingredient, sugar or sugar alcohol, binders, disintegrants, and other excipients. The dosage form can be a tablets and capsules. They can also be a microgranule, granules, particles, and microparticles; wherein these forms are collectively termed "microcapsules" in the teaching and Siebert also teaches that all these forms need not be coated at all (Col. line 39-50). Siebert also teaches powders which can be coated or uncoated (Col.4 line 47-68). These granules/microcapsules can also form larger forms such as tablets. The active include pharmaceutical ingredients and the formulation is particularly capable of taste masking distasteful drug particles. The sugar or sugar alcohol preferably includes mannitol. The binders preferably include microcrystalline cellulose, starch, and methyl cellulose. Desirable disintegrants include crospovidone. Example 1 is a powder (granular) composition comprising famotidine, mannitol, microcrystalline cellulose (Avicel), and crospovidone that is formed into a tablet. The ratios for famotidine, mannitol, and binder are based on the amounts of each component. The amount of water is negligible as it is evaporated during granulation. There is 9.09mg of famotidine, 30mg microcrystalline cellulose, and 151.1mg mannitol

in the tablet. The ratio of famotidine to the binder is 9.09:30 or 1:3.3. The ratio of binder to mannitol is 30:151.1 or 1:5.04.

The disintegration properties and profiles are intrinsic to the composition. When the components of compositions are met, the properties related to it are the same. The composition is prepared by creating a coating solution (water-containing solvent comprising ethyl cellulose and HPMC-both binders), the drug (famotidine), is screened, coated while granulated, blending with mannitol, binder, disintegrant, other excipients, screened, mixed, powder is discharged, then tableted (see full document, Abstract, Col. 2 line 13-Col. 4 line 58, Col. 5 line 1-48, Col. 6 line 46-63, Col. 7 line 7-50, Example 1). It is noted that the phrase consisting essentially of does not limit the components of the composition as the elements are all used for the same purpose which is a pharmaceutical form with improved organolepic properties, where they do not materially change the purpose of the composition.

Siebert et al. does not expressly teach methylcellulose in the example or an example of a granule form of the composition.

However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute methylcellulose for microcrystalline cellulose, as suggested by Siebert, and produce the instant invention. Siebert teaches that the preferred binders include microcrystalline cellulose and methyl cellulose. It would have be obvious to one of skill in the art to substitute one preferred binder for another depending on availability or desired properties as they are taught to be analogous. It is also obvious to form granules as taught by Siebert (forms taught

include granules, particles, microparticles, powder, tablets) with the formulations presented such as in Example 1 by granulation with the same granulation process taught by Siebert in Example 1 with the same aqueous solvent presented (water with binders), as it is within the skill of one in the art and these minor variations are routinely practiced in the art to determine the best therapeutic efficacy and profile for the best outcome in the final product.

One of ordinary skill in the art would have been motivated to do this because it is desirable for manufacturers to have functionally equivalent choices to substitute the binders when motivated by pricing, availability, or desired properties of the binder used to produce the final product. It is also desirable to have different forms of the same product for different modes of delivery dependent on the profile desired.

10. Claims 8-10, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siebert et al. (U.S. Pat. No. 6368625) as applied to claims 1, 4, 6-7, 11, 13-20, 22-23 above, in view of Depui et al. (U.S. Pat. No. 6132771) and further in view of Yoshinari et al. (U.S. Pat. No. 6235947).

The teachings of Siebert et al. are addressed above.

Siebert et al. does not expressly teach the incorporation of D-mannitol or mosapride (4-amino-5-chloro-2-ethoxy-N—[[4-(4-flurobenzyl)-2-morpholinyl]-methyl]benzamide) or a commercial package.

Depui et al. teaches the usefulness and incorporation of mosapride for the treatment of gastro oesophageal reflux disease (GORD, also known as GERD). Depui

also teaches that famotidine is known to be used for GORD/GERD (Abstract, Col.1, lines 20-33, 50-65, Col.2, lines 2-4, Col. 7, lines 55-68, Col. 8, lines 1-5, Examples).

Yoshinari et al. teaches that D-mannitol is of high value as an excipient for high moisture sensitivity as it is not hygroscopic and retains no substantial moisture. The D-mannitol produced has excellent compressibility and has versatility as it can be used for direct compression, wet-granulation, or dry-granulation. It can be used as a good excipient for pharmaceutical compounds (Abstract, Col. 1, lines 10-17, Col.4, lines 19-50, Col.8, lines 1-20).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute mosapride for famotidine and D-mannitol for mannitol, as suggested by Depui and Yoshinari, and produce the instant invention. Mosapride and famotidine as both used for GORD as taught by Depui, known to have unpleasant tastes (see Siebert above and Yoshioka et al. (WO 2004/066913), pages 2-3), so it would have been obvious to one of skill in the art to substitute mosapride for famotidine as it is routine to use known formulations for analogous drugs, with a reasonable expectation of success. As the composition of Siebert is disintegrable, and thereby sensitive to humidity, it would be obvious to substitute the mannitol with D-mannitol as Yoshinari teaches that D-mannitol is desirable as an excipient for high moisture sensitivity formulations as it is not hygroscopic and retains no substantial moisture. It is noted that when the components of the composition are met, the properties intrinsic to the composition are met.

It is also obvious to place any composition in a package to not only designate what the composition is through labeling, but also for storage, shipping, and stability to stores, pharmacies, and consumers. Written matter for the use of a known drug (mosapride), particularly for an existing use, does not impart patentability. An example of this is a disintegrating tablet formulation of mosapride in a Press Through Pack package disclosed in Shirai et al. (U.S. Pat. No. 6413541, Col. 2, lines 55-65) or packaging of Yoshioka et al.

One of ordinary skill in the art would have been motivated to do this because it is desirable for manufacturers to optimize the same formulation for analogous drugs to reduce the amount of experimentation, research, and development to lower cost and improve efficiency. It is also desirable to use similar and analogous drugs for the same purpose for composition formulation when motivated by pricing, availability, or desired properties of the final product. It is also desirable for manufacturers place any composition in a package to maintain stability (humidity-desiccants), reduce breakage, and increase ease of storage and shipping to stores, pharmacies, and consumers. Thereby reducing production costs (less breakage and spoilage) and improving acceptable of consumers and distributors. Written matter for the composition, is desirable for manufacturers to ensure that the composition is taken appropriately.

11. Claims 1, 4, 6-7, 11, 13-15, 17-20, 22-24, 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Debregeas et al. (U.S. Pat. Pub. 2004/0081691) in view of Nishii et al. (U.S. Pat. 6517870).

Debregeas et al. teaches granules with taste masking containing a plant substance, a neutral core such as mannitol, starch (a disintegrant), talc, and mixtures thereof, and a binder such a polyvinylpyrrolidone (PVP) or hydroxypropylmethylcelllulose (HPMC) (Abstract, paragraph 10, 12, 21-22, 24-27). The granules can be packaged into gelatin capsules (pill-paragraph 8). Alcoholic or aqueous-alcohol solutions with the binder and the extract can be used. Example 1 teaches granules formed by granulation with the binding/coating solution consisting of green tea extract (unpleasant tasting active-49.9-52.3%), neutral core (e.g. mannitol,40-42.2%), PVP (polymer, 4.5-6.7%), and talc (paragraph 50-55, claims). The ratio for active/polymer parts= 1: 7.45-11.62; ratio of polymer/mannitol parts: 1:5.97-9.37 which encompass and are within the claimed ratios respectively.

Debregeas does not teach an example with methylcellulose.

Nishii et al. teaches that functionally equivalent binders in tastemasking include HPMC, PVP, and methylcellulose (Col.2 line 49-51).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to optimize the amounts in the example and arrive at the ratios, substitute methylcellulose for PVP in the Example, as suggested by Nishii, and produce the instant invention. It is obvious to substitute one functional equivalent binder/polymer for another as it is desirable to have alternatives based on pricing, availability, or desired properties of the binder/polymer. Absent any evidence of criticality of the ratios for medicament/methylcellulose being 1part: about 0.8-about 10

parts, and the ratios for methylcellulose/mannitol being 1part: about 0.3-about 12 parts, the adjustment of components within the taught ranges is not inventive. Additionally, selection of any order of performing process steps (e.g. methylcellulose/binder(polymer)) in water or separate from the water for granulation) is *prima facie* obvious in the absence of new or unexpected results.

12. Claims 1, 4, 6-7, 11, 13-20, 22-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alkire et al. (U.S. Pat 5607697).

Alkire et al. teaches taste masking microparticles for oral dosage forms. The microparticle has a core with a pharmaceutical with an objectionable taste, a binder, and a sugar alditiol such as mannitol (Abstract, Col. 2 line 55-Col. 3 line 16, claims). The particle can include other excipients. The active amount varies generally ranging from about 0.1 to 2000mg that can be between about 0.1-about 67% of the dosage form, the sugar alditiol such as mannitol is from zero to about 80% of the microparticle (Col. 4 line 55-Col. 7 line 43). The drug and sweetener may be combined by wet granulation, dry granulation , agglomeration, spray coating, or mixing. Binder/polymer coat include PVP and methylcellulose and are at least about 5% of the microparticle (Co.. 7 line 5-23). The other adjuvants for the particle and the final dosage form included binders and disintegrants (e.g. effervescent, starch, microcrystalline cellulose, Avicel, alginic acid-Col. 6 line 61-Col. 7 line 5, col. 8 line 43-50, 55-col.10 line 65). Example 1 and Table 4 teaches particles/granules formed from granulation/coating/granulation consisting of the bitter drug (chlorpheniramine-50mg,

dextromethophan-200mg), mannitol (930mg, 750mg), and PVP(20mg, 50mg). Table A teaches a tablet formulation with the particles.

Alkire does not expressly teach an example with methylcellulose or the claimed ratios. However, Alkire does teach that the binder/polymer can be methylcellulose, the amount of polymer are at least about 5% of the microparticle and the mannitol is from zero to about 80% of the microparticle; wherein it would be obvious to one of skill in the art to substitute the methylcellulose for the PVP and optimize the amount of mannitol and polymer in the ranges taught to arrive at the ratios as it is obvious to substitute one functional equivalent binders/polymers for another as Alkire teaches their equivalence and absent any evidence of criticality of the ratios for medicament/methylcellulose being 1part: about 0.8-about 10 parts, and the ratios for methylcellulose/mannitol being 1part: about 0.3-about 12 parts, the adjustment of components within the taught ranges is not inventive. Additionally, selection of any order of performing process steps (e.g. methylcellulose/binder(polymer)) in water or separate from the water for granulation) is *prima facie* obvious in the absence of new or unexpected results.

13. Claims 8-10 and 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alkire et al. (U.S. Pat 5607697) as applied to claims above, in view of Depui et al. (U.S. Pat. No. 6132771), MIMS (Gasomotin®), and Yoshinari et al. (U.S. Pat. No. 6235947).

The teachings of Alkire et al. are addressed above.

Alkire et al. does not expressly teach the incorporation of D-mannitol or mosapride (4-amino-5-chloro-2-ethoxy-N—[[4-(4-flurobenzyl)-2-morpholinyl]-methyl]benzamide) or a commercial package.

Depui et al. teaches that mosapride is a known and available pharmaceutical and MIMS teaches that mosapride is known to have a bitter taste (Description).

Yoshinari et al. teaches that D-mannitol is of high value as an excipient for high moisture sensitivity as it is not hygroscopic and retains no substantial moisture. The D-mannitol produced has excellent compressibility and has versatility as it can be used for direct compression, wet-granulation, or dry-granulation. It can be used as a good excipient for pharmaceutical compounds (Abstract, Col. 1, lines 10-17, Col.4, lines 19-50, Col.8, lines 1-20).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate mosapride in the composition of Alkire as Depui teaches that mosapride is a useful pharmaceutical and mosapride is known to be bitter as evidenced by MIMS, and Alkire teaches the composition to be useful for any pharmaceutical for tastemasking wherein it is obvious to use the Alkire composition for a drug known to be bitter to mask the undesirable taste with a reasonable expectation of success. It also would have been obvious to substitute the D-mannitol for mannitol, as suggested by Yoshinari, and produce the instant invention. As the composition of Alkire is disintegrable particularly in the final tablet form, and thereby sensitive to humidity, it would be obvious to substitute the mannitol with D-mannitol as Yoshinari teaches that

D-mannitol is desirable as an excipient for high moisture sensitivity formulations as it is not hygroscopic and retains no substantial moisture. It is noted that when the components of the composition are met, the properties intrinsic to the composition are met.

It is obvious to place any composition in a package to not only designate what the composition is through labeling, but also for storage, shipping, and stability to stores, pharmacies, and consumers. Written matter for the use of a known drug (mosapride), particularly for an existing use, does not impart patentability. An example of this is a disintegrating tablet formulation of mosapride in a Press Through Pack package disclosed in Shirai et al. (U.S. Pat. No. 6413541, Col. 2, lines 55-65) or packaging of Yoshioka et al. It is also desirable for manufacturers place any composition in a package to maintain stability (humidity-desiccants), reduce breakage, and increase ease of storage and shipping to stores, pharmacies, and consumers. Thereby reducing production costs (less breakage and spoilage) and improving acceptable of consumers and distributors. Written matter for the composition, is desirable for manufacturers to ensure that the composition is taken appropriately.

Response to Arguments

14. Claim 1, 4, 6-7, 11, 13-20, 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siebert et al. (U.S. Pat. No. 6368625).

Applicant's arguments filed 2/18/2010 have been fully considered but they are not persuasive. Applicant's arguments are directed to the assertion that the term "consisting essentially of" excludes unnamed material form the claims that mask the

unpleasant taste of the medicament. This is not persuasive as the phrase consisting essentially of does not limit the components of the composition as the elements are all used for the same purpose which is a pharmaceutical form with improved organolepic properties, where they do not materially change the purpose of the composition.

In regards to the declaration of Dr. Shimono, the declaration is fully considered but is not commensurate in scope with the claims as written. Both particles in Table 2 exhibited the tastemasking and Applicant cites that the microcrystalline cellulose particle was felt verses the methylcellulose which is not felt, which is not entirely reflective of the Table which states that the methylcellulose particle is not felt but the microcrystalline cellulose particle "was not almost felt". As a result, they both accomplished the tastemasking and modification of sensation by degrees which is not unexpected as both formulations showed taste masking properties which given the teachings of Siebert that methylcellulose and microcrystalline cellulose are functional equivalents and allows for the use of either polymer for the tastemasking dependent on the properties desired. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious.

However, in regards to the declaration that the tastemasking is present with the mannitol, methylcellulose, and drug with the ratios such that it is not necessary to use special techniques such as coating and microcapsulation, this is reconsidered and is persuasive but is not commensurate in scope with the claims as written and requires additional evidence. Many of the claims as written allow for additional excipients which

are not commensurate in scope but are commensurate in scope with claim 25 which is to the drug, mannitol, and methylcellulose in the claimed ratios. The claims as written allow for binding solutions (e.g. water containing solvent) that are utilized in coating particles and encapsulation which is a different scope than the declaration, and the composition claims do not currently contain an absence of a coating. This lack of coating may be present in the particles formed in the examples in the specification and the declaration which have the drug, methylcellulose, and mannitol are together and are granulated only with water to form the granule in these ratios. However additional evidence would be needed to show that this is the case and a coating would not be inherently formed when producing in this manner (e.g. not a coating but an agglomerate granule) and the granule formation would be different than when the methylcellulose is present in the water during granulation which would yield a coating as addressed by the declaration. If the these elements (e.g. no coating as suggested by the declaration) are present in a granule consisting of the drug, mannitol, methylcellulose with evidence as suggested above in the ratios claimed, it can be helpful in showing the distinctiveness of the application. Addressing the criticality of the ratios in addition is also helpful. The claims as written are not reflective of the showing and the showing requires additional clarification.

Accordingly, the rejection is maintained.

15. Claims 8-10, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siebert et al. (U.S. Pat. No. 6368625) as applied to claims 1, 4, 6-7, 11, 13-20, 22-

23 above, in view of Depui et al. (U.S. Pat. No. 6132771) and further in view of Yoshinari et al. (U.S. Pat. No. 6235947).

Applicant's arguments filed 2/18/2010 are directed to Siebert which is addressed above. Accordingly, the rejection is maintained.

Conclusion

16. Claims 1, 4, 6-11, 13-27 are rejected.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-

9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G. H./
Examiner, Art Unit 1612
/Zohreh A Fay/
Primary Examiner, Art Unit 1612